DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 25, 2014

North East Monitoring, Inc.
c/o Mr. Joe Azary
Official Correspondent
2 Clock Tower Place, Suite 555
Maynard, Massachusetts 01754

Re: K142424
Trade/Device Name: DR300 Holter Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: October 3, 2014
Received: October 6, 2014

Dear Mr. Joe Azary,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): __K142424_____

Device Name: __ DR300 Holter Monitor____

Indications For Use:

Holter Mode: Detection of Arrhythmias, Efficacy of Pharmacological Treatment and Pacemaker Evaluation.

Event Recorder: The event recorder module is a patient activated device designed to record and for diagnostic evaluation of transient symptoms (such as dizziness, palpitations, syncope, and chest pain). Once data is recorded, the data is transmitted for evaluation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

510(k) Summary
for North East Monitoring
DR300

1. SUBMITTER/510(K) HOLDER

North East Monitoring
Two Clock Tower Place
Suite 555
Maynard, MA 01754

Contact Name: Joseph Azary
Email: jazary@erols.com
Telephone: (203) 242-6670

Date Revised: November 4, 2014

2. DEVICE NAME

Proprietary Name:	DR300 Holter Monitor
Common/Usual Name:	Ambulatory ECG recorder, Ambulatory Electrocardiograph (without analysis), Holter Monitor
Classification:	Class 2, 21 CFR 870.2800
Classification Name:	Ambulatory ECG recorder
Product Code:	MWJ

3. PREDICATE DEVICES

- K061293 Telaheart Digital Recorder / DR200

4. DEVICE DESCRIPTION

The DR300 is an ambulatory monitor, sometimes called a Holter, which is a painless method to monitor the heart beat for a period of time (such as 24 hours, 48 hours, or 72 hours). The Holter is a small recording device that records the heart beat while being worn by the patient.

The physician or technician places electrodes and wires on the patient. The wires are connected to the Holter or digital recorder.

The DR300 Recorder has two modes that allow it to be used either as a standard Holter monitor or a looping Event recorder. The device is designed to facilitate ambulatory cardiac monitoring on the order of a physician, of those patients (including infants weighing less than 10 kg) who may benefit from such monitoring.

The data obtained during monitoring is not analyzed at the time of recording. After the recording is complete, the data must later be downloaded to a compatible NorthEast Monitoring Holter or Event analysis system (TelePro Software) to be analyzed. The Holter Analysis Software was cleared by FDA under K930564.

The device is not intended to replace real time telemetry monitoring for patient suspected of having life threatening arrhythmias.

The DR300 Digital Recorder package includes:

- DR300 Digital Recorder
- Operation Manual
- SD Card
- Patient Cable

The DR300 digital recorder is powered by one 1.5 volt AA alkaline battery (MN1500 or the equivalent), one AA rechargeable NiMH (nickel metal hydride) battery, or one AA Eveready Lithium L91 battery. Batteries should not be re-used for a second patient. The batteries are not included; users are instructed to purchase 2 AA batteries.

The device is compatible with standard silver / silver chloride ECG electrodes. Electrodes are not provided with the subject device. The user is instructed to purchase standard silver / silver chloride ECG electrodes.

The DR300 digital recorder uses NorthEast Monitoring NorthEast Monitoring shielded patient cables with either 5 or 7 patient leads for a 3 channel recording or three leads for 2 channel Holter Recording.

The DR300 has an LCD that is used to display the time of day (during the recording), prompts and error messages (during the hookup procedure or during recording), or lead quality (during the hookup procedure).

The data collected by the DR300 digital recorder is stored on a removable SD Card.

The DR300 is packaged in a plastic bag in a cardboard shipping carton. The shipping carton will also include a patient cable and an SD Card.

The difference between the DR300 and the DR200/Telaheart is the wireless capability. The DR300 digital recorder is equipped with wireless Bluetooth transmitter. A NorthEast Monitoring Bluetooth Gateway or USB Dongle is able to receive the encrypted Holter and Event data.

In order for the wireless transmission to occur, the DR300 will need to come in range of a North East Monitoring transceiver – either a gateway or a PC with a USB Adapter. If there is sufficient data to send, the recorder will attempt to locate a transceiver every 20 minutes. When the transceiver is found the data will be sent. Transmission may be started manually by pressing the enter button.

5. INTENDED USE

The DR300 Digital Recorder can be used in Holter mode and Event Recorder mode.

Holter Mode

Detection of Arrhythmias, Efficacy of Pharmacological Treatment, and Pacemaker Evaluation.

Event Recorder

The DR300 event recorder module is a patient activated device designed to record and for diagnostic evaluation of transient symptoms (such as dizziness, palpitations, syncope, and chest pain). Once data is recorded, the data is transmitted wirelessly for evaluation.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The DR300 substantially equivalent to the Telaheart / DR 200 cleared under 510(k) K061293. The DR300 is equipped with a wireless Bluetooth transmitter and has additional shielding to be immune to radiofrequency interference and in order to pass FCC and EMC test requirements.

When the wireless function is enabled by the physician/technician, once every preset interval (normally set at 20 minutes) the device will check for the availability of any new data since the last successful transmission. If there is any, the Bluetooth module will be enabled and an attempt made to establish a link. If a link is established, then all available new ECG data will be transmitted. After each "block" of data is transmitted (normally 16 K bytes or less) a verification will be made for a successful transmission by the detection of a reply from the receiving end. The data will be re-transmitted if needed.

7. PERFORMANCE TESTING

The subject device conforms to the following standards:

- IEC 60601-1-6: 2010 Medical Electrical Equipment Part 1-6: General Requirements for Safety – Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices.
- IEC 60601-1-11: 2010 Medical Electrical Equipment Part 1-11: General Requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1: 2012 Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 60601-1-2-47 Medical Electrical Equipment Part 2 – 47: Particular Requirements for the Safety including Essential Performance of Ambulatory Electrocardiographic Systems.
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility.
- FDA Guidance Radio Frequency Wireless in Medical Devices (August 14, 2013)

8. SAFETY AND EFFICACY

The subject device was subjected to testing including:

- IEC 60601-1-6: 2010 Medical Electrical Equipment Part 1-6: General Requirements for Safety – Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices.
- IEC 60601-1-11: 2010 Medical Electrical Equipment Part 1-11: General Requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1: 2012 Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 60601-1-2-47 Medical Electrical Equipment Part 2 – 47: Particular Requirements for the Safety including Essential Performance of Ambulatory Electrocardiographic Systems.
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility.
- Software Verification and Validation
- Simulated bench and wireless testing (see summary below)

The testing included 11 Holter Tests for the purposes of verifying that the DR300 functions as intended. Testing was conducted related to the functionality of the Holter and Event functions of the DR300 without the wireless function being utilized. These tests verified that the device functions as intended after the inclusion of the Bluetooth transmitter and additional shielding. The testing ranged from monitoring over a 24 hour to 14 day period. Additional testing was performed to evaluate the wireless Bluetooth technology and communication of encrypted data. The wireless testing ranged from monitoring over a 24 hour to 48 hour period.

All testing confirmed that the device using the wireless technology functioned as intended and found no issues of safety or effectiveness.

9. CONCLUSION

North East Monitoring believes that based on the indications for use, technological characteristics, and comparison to predicate devices the DR300 has been shown to be substantially equivalent to the predicate.